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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,663	03/05/2002	Helmut Eckert	900-9638D	8183

7590 01/16/2004

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,663	ECKERT ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-28 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 and 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 13-19, 23 and 28) in the Paper received October 22, 2003 is acknowledged. The traversal is on the ground(s) that Group II claims should be rejoined with the claims of Group I and a prior search for Group I will identify prior art for Group II. This is not found persuasive because these groups are classed separately. Clearly different searches and issues are involved in the examination of each group. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. For these reasons the restriction requirement is deemed to be proper and is adhered to. Applicant is reminded that the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed.

However, the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed. Method claims limited to the scope of the allowable product claims will be rejoined and examined at the time the product claims are indicated as being allowable..

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 13-28 are pending.

Claims 20-22 and 24-27, drawn to non-elected inventions, are withdrawn from examination.

Claims 13-19, 23 and 28 are examined on the merits.

Art Unit: 1642

3. The declaration submitted under 37 CFR 1.132 filed February 24, 2003 is insufficient to overcome the rejection of claims 13 based upon the prior art references applied under 35 U.S.C. 102 and 103 as set forth in the instant Office action because: of the reasons set forth below in paragraphs 7 and 9 on pages 3-6.

Information Disclosure Statement

4. The information disclosure statement filed November 29, 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because sheet 6 contains document listings that do not have publication dates and one of skill in the art would not be able to retrieve these articles based on the limited information provided. Furthermore, the parent application, as well as the continuing applications were not available to the Examiner at the time of examination. Accordingly, not all documents noted on the eight sheets of the IDS filed November 29, 2002 were not considered and will review these documents when they are accessible.

Oath/Declaration

5. It is not clear whether or not the oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying the foreign applications by corresponding application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration may be defective because: it lists three United Kingdom applications, one of which is **9210944.6**, filed May 22, 1996, however the Application

Art Unit: 1642

Data sheet cites **92109.44**, filed May 22, 1992. Applicants are requested to properly identify the foreign application and correct all documents listing the erroneous foreign application number.

Claim Objections

6. Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 13 reads on an anti-idiotypic antibody product that binds a breast cancer cell line and dependent claim 16 reads broadly on cancer cells of epithelial origin. As such claim 16 reading broadly on all cancer cell of epithelial origin is not further limiting from the said independent claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 13-19, 23 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Loibner et al. (Abstract from 7th International Congress of Immunology, Berlin, July 30-August 5, 1989/ IDS Reference, filed page 3, November 29, 2002 and February 24, 2003).

In anticipation of the instant rejection Applicants have submitted a declaration and argue "the Loibner reference only teaches producing a mixture of antibodies and this reference, alone or in combination...does not teach the instant invention." The declaration has been fully review and Applicants' points of view have been considered, but found unpersuasive.

As submitted by Applicants Loibner discloses an immunization technique. Loibner also discloses anti-idiotypic antibodies against BR55-2 useful for active tumor immunotherapy produced by the said technique, see title. The disclosed anti-BR55-2 antibodies bind the Y-tetrasaccharide antigen, which is expressed on the surface of human adenocarcinoma cells of breast, colon and lung. The Lewis Y (Le(y)) antigen is a difucosylated tetrasaccharide and accordingly these molecules are one in the same would bind the same binding moieties. These anti-idiotypic antibodies read on the claims. It is the Examiner's position that these disclosed antibodies would act in the same manner as those claimed, i.e. retain equivalent inhibition capacity and produce immune response against Lewis Y carbohydrate-expressing cells.

Since the Patent and Trademark Office does not have the facilities for examining and comparing the disclosed anti-idiotypic antibodies of Loibner and the anti-idiotypic antibodies of the claimed invention the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the antibodies in the claimed invention to be used in the claimed methods of the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 13-19, 23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 4,971,792 (issued November 20, 1990)/ IDS Reference on sheet 1 of , filed November 29, 2002 and September 22, 2003).

In anticipation of the instant rejection Applicants have submitted a declaration and aver that "The Potocnjak reference does not describe the criteria of the screen and without these criteria, one cannot guarantee obtaining an antibody suitable for medical purposes". The declaration has been fully review and Applicants' points of view have been considered, but found unpersuasive.

U.S. Patent #4,971,792 teaches monoclonal antibodies BR55-2 (ATCC HB 9324), which bind to malignant cells expressing on or more determinants such as Y-6 and B-7-2. The patent does not teach monoclonal murine internal anti-idiotypic antibodies to the said monoclonal antibodies designated as BR55-2. However, the patent '792 states "The isolation of other hybridomas secreting monoclonal antibodies with the specificity of the monoclonal antibodies of the invention can be accomplished by one of ordinary skill in the art by the technique of anti-idiotypic screening (Potocnjak, et al., *Science*, 215:1637, 1982).", see column 3, lines 10-40. Furthermore, the patent

Art Unit: 1642

provides methods for ameliorating malignant disease in an animal using the taught monoclonal antibodies. And while Potocnjak does not describe the particulars of the screening criteria there is no evidence presented that would lead one of ordinary skill in the art to believe the anti-idiotypic antibodies utilizing the technique of Potocnjak would not act in the same manner as those claimed. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to produce anti-idiotypic antibodies specific for monoclonal antibodies BR55-2 and utilize in methods of cancer immunotherapy. The produced antibodies would intrinsically act in the same manner as those claimed, i.e. retain equivalent inhibition capacity and produce immune response against Lewis Y carbohydrate-expressing cells. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the recited patent as well as the fact that anti-idiotypic responses are complementary to antibody responses since they both play roles in regulating humoral and cell-mediated immunity.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone

Application/Control Number: 10/090,663

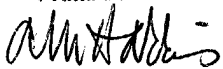
Page 8

Art Unit: 1642

number for the organization where this application or proceeding is assigned is (703) 308-4315.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
11 January 2004